

Translation

PATENT COOPERATION TREATY

PCT/EP2003/009102



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000053862	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/009102	International filing date (<i>day/month/year</i>) 18 August 2003 (18.08.2003)	Priority date (<i>day/month/year</i>) 20 August 2002 (20.08.2002)
International Patent Classification (IPC) or national classification and IPC C12P23/00, C12N15/82, C12N9/14, C12N9/02, C12N9/90		
Applicant SUNGENE GMBH & CO.KGAA		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 18 March 2004 (18.03.2004)	Date of completion of this report 03 November 2004 (03.11.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/009102

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages _____ 1-188 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____ 1-100 _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the drawings:
pages _____ 1/47 - 47/47 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages _____ 1-244 _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/E0 30/09102

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 10, 11, 13, 17-67, 69, 70, 74, 76-85, 91-95	YES
	Claims	1, 3-9 12, 14-16, 68, 71-73, 75, 86-90, 96-100	NO
Inventive step (IS)	Claims		YES
	Claims	1-100	NO
Industrial applicability (IA)	Claims	1-100	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following documents:

- D1: WO 03/080849 A (BALL HORTICULTURAL COMPANY)
2 October 2003
- D2: WO 98/18910 A (YISSUM RES DEV CO (IL))
7 May 1998
- D3: DATABASE UNITPROT [Online] 1 March 2002
(2002-03-01), KANEKO, T. ET AL.: "Beta-carotene ketolase", found in EBI accession no. Q8YSA0, Database accession no. Q8YSA0
- D4: WO 00/32788 A (HANSEN)
8 June 2000
- D5: WO 99/07867 a (CALGENE LLC)
18 February 1999
- D6: WO 00/61764 A (BASF AG)
19 October 2000
- D7: WO 99/63055 A (UNIV MARYLAND (US))
9 December 1999
- D8: WO 99/61652 A (UNIV MARYLAND)
2 December 1999.

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2. Novelty and inventive step (PCT Article 33(2) and (3)):

- 2.1 Document D1, classified as an E document in the search report, has been disregarded for the purpose of the examination since the priority of the application was assumed to be valid.
- 2.2 Document D2 discloses (see pages 18-20, 28-29, 31-32 and 38-41) transgenic plants that express beta-carotene oxygenase (ketolase) from *Haematococcus pluvialis* in chromoplasts and, hence, in flowers also (see D2, claim 68 and page 39), using a construct that is identical to one of the constructs according to the application, in other words that is identical to a chromoplast promoter and a chromoplast transit peptide.

In consequence, D2 is prejudicial to the novelty of claims 1, 3-9, 12, 14-16, 68, 71-73, 75, 86-90 and 96-100.

- 2.3 An inventive step can be acknowledged if the subject matter of an (independent) claim solves a technical problem in a non-obvious manner.

Therefore, the following conditions must be satisfied:

- i) there must be a problem;
- ii) said problem must be solved for the entire scope of the claim;

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- iii) all the features that contribute to the solution must be contained in the independent claim; and
- iv) the solution must not be obvious.

The problem addressed by the present invention (see page 2, lines 14-20) consists in developing an alternative method for producing ketocarotenoids by plant cultivation and developing further ketocarotenoid-producing transgenic plants, said plants having **optimised** properties - for example a higher ketocarotenoid content.

In claim 1, a system for solving said problem is described in very general terms. Although a number of embodiments are defined in greater detail in the description, the applicant has failed to show that these embodiments, or at least one thereof, also actually solve(s) the problem, that is to say have (has) optimised properties relative to the prior art - for example increased ketocarotenoid content or improved purity. Moreover, there are no examples relating to the subject matter of claims 2 and 29-61. Thus, conditions ii) and iii) are not satisfied and an inventive step cannot be acknowledged; in other words, it is not possible to establish whether or not an inventive step is involved until conditions ii) and iii) are satisfied.

- 2.4 Irrespective of the above objections, the applicant is advised that, even were the independent claims to be rendered novel by combination with a (novel)

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dependent claim, said combination would still not be inventive, since dependent claims 2, 10, 11, 13, 17-67, 69, 75 and 76-85 contain no features which, combined with the features of any claim to which they refer, meet the PCT requirements for inventive step (see documents D3-D8 and the corresponding passages of text cited in the search report).

3. Clarity (PCT Article 6)

3.1 The term "ketolase", used in the claims, is vague and lacks clarity, leaving the reader uncertain as to the meaning of the technical feature in question. The term used by a person skilled in the art is "beta-C4-4-oxygenase" or "4-4'-oxygenase".

3.2 The broadest claim is claim 12, not claim 1.